IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	HOLDSTOCK et al.	Examiner:	William K. Cheung
Application Number:	09/977,880	Group Art Unit:	1796
Filed:	October 15, 2001	Confirmation No.:	3435
Docket No.:	674515-2003 (3038-013)	Customer No.:	81693

For: PROCESS FOR THE PREPARATION OF A DIOL

APPEAL BRIEF
UNDER 37 C.F.R. § 41

Mail Stop **Appeal Brief — Patents**
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

July 17, 2009

Sir:

(1) Identification

The appellants, application, and the Examiner's identification data associated with this paper are provided in the above-captioned heading.

The appellants hereby file an Appeal Brief under 37 C.F.R. § 41.37, together with the applicable fee under 37 C.F.R. § 41.20(b)(2).

A Notice of Appeal under 37 C.F.R. § 41.31 was previously filed on May 19, 2009, together with the applicable fee.

(2) Table of Contents

(3) Real Party in Interest

The real party in interest in this case is *CooperVision International Holding Company LP*, the assignee of record.

(4) Related Appeals and Interferences

The appellants are not aware of any other appeals or interferences that will directly affect, be directly affected by, or have a bearing on the Board's decision in the present appeal.

(5) Status of Claims

Claims 7-8 and 27-28 are canceled.

Claims 1-6, 9-26, 29, and 30 are rejected.

No claim is withdrawn.

Claims 1-6, 9-26, 29, and 30 are on appeal.

(6) Status of Amendments

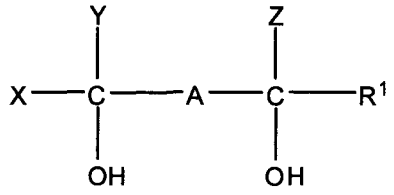
No amendment was filed subsequent to the final Office Action dated February 25, 2009.

(7) Summary of Claimed Subject Matter

I. Concise Explanation of the Subject Matter Defined in Independent Claims and Separately Argued Dependent Claims

a) Independent Claim 1

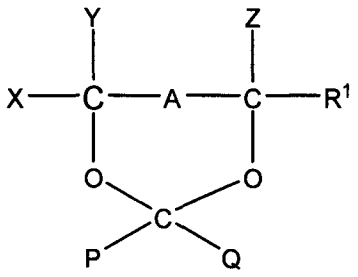
Claim 1 is directed to a process for the preparation of a polymerizable composition comprising a polymerizable monomer of formula I (page 5, lines 12-16; page 10, lines 15-19):



(I)

the process comprising the steps of (page 5, line 16; page 10, line 20):

(i) contacting a compound of formula II (page 5, lines 18-21; page 10, lines 22-24)



(II)

with an immobilized acid to thereby form a composition comprising the monomer of formula (I) and an acid by-product thereof (page 5, line 22; page 10, line 25)

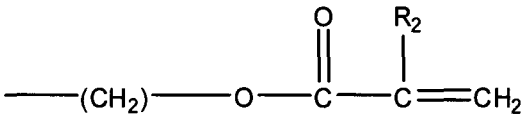
wherein

X, Y, Z, P, and Q are independently selected from a hydrocarbyl group or hydrogen (page 5, lines 23-24; page 7, lines 14-23; page 9, lines 27-28; page 10, line 26 to page 11, line 5),

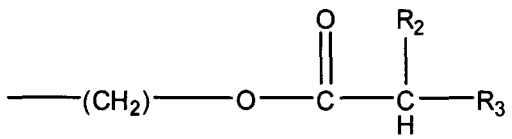
A is $(CH_2)_n$, wherein n is 0 or 1 (page 5, line 24; page 11, line 3);

R^1 corresponds to either formula IIIA or formula IIIB (page 9, lines 21-23; page 10, lines 4-

5; page 11, lines 6-10)



IIIA



IIIB

where R_2 is selected from the group consisting of H, methyl, ethyl, propyl, and butyl (page 9, lines 24-25; page 11, line 9), and

and

R_3 is an unsaturated C_{2-5} alkyl (page 9, lines 24-25; page 11, line 9; page 21, lines 13-14); and

(ii) neutralizing the composition of step (i) with an immobilized hydroxide, to thereby provide a composition comprising the monomer of formula I and a cross-linker (page 5, line 26; page 7, lines 5-7; page 11, lines 11-12).

b) Dependent Claim 9

Claim 9, which depends from claim 1, further recites that prior to the contacting, the immobilized acid is contained, and after said contacting, passing a gas through the contained immobilized acid (page 11, lines 25-27; page 12, lines 7-9; page 18, lines 1-2; page 21, lines 21-23).

c) Dependent Claim 18

Claim 18, which depends from claim 15, which depends from claim 1, further recites forming the polymer formed in the polymerizing step into an ocular device (page 12, lines 24-30; page 26, lines 14-15).

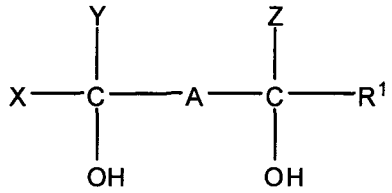
d) Dependent Claim 21

Claim 21, which depends from claim 15, which depends from claim 1, further recites an

ocular device comprising the polymer formed by the process of claim 15 (page 6, lines 1-2; page 12, lines 24-30; page 18, line 20 to page 19, line 9; page 22, lines 28-29; page 23, lines 4-9; page 26, line 23).

e) Independent Claim 22

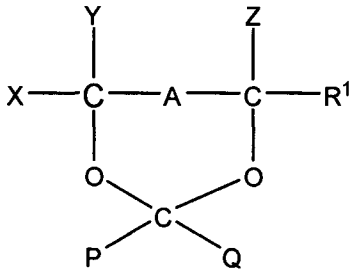
Claim 22 is directed to a process for the preparation of a polymerizable composition comprising a polymerizable monomer of formula I (page 5, lines 12-16; page 10, lines 15-19):



(I)

said process comprising the steps of (page 5, line 16; page 10, line 20):

(i) contacting a compound of formula II (page 5, lines 18-21; page 10, lines 22-24)



(II)

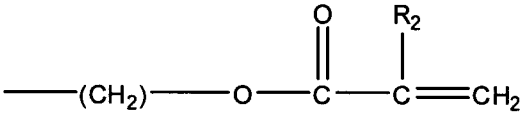
with an immobilized acid having a pK_a of less than 3 to thereby form a composition comprising the monomer of formula (I) and an acid by-product thereof (page 5, line 22; page 6, lines 29-30; page 10, line 25),

wherein

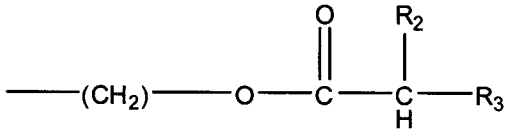
X and Y are independently selected from hydrocarbon groups having 1 to 20 carbon atoms and hydrogen (page 8, lines 1-5, 15, 20; page 9, lines 7-17; page 9, line 29 to page 10, line 1; page 10, line 26 to page 11, line 1),

Z, P, and Q are independently selected from a hydrocarbyl group or hydrogen (page 5, lines 23-24; page 9, lines 26-27), A is $(CH_2)_n$, wherein n is 0 or 1 (page 5, line 24; page 11, line 3);

R^1 corresponds to either formula IIIA or formula IIIB (page 9, lines 21-23; page 10, lines 4-5; page 11, lines 6-10)



IIIA



IIIB

where R_2 is selected from the group consisting of H, methyl, ethyl, propyl, and butyl (page 9, lines 24-25; page 11, line 9), and

R_3 is an unsaturated C_{2-5} alkyl (page 9, lines 24-25; page 11, line 9; page 21, lines 13-14); and

(ii) neutralizing the composition of step (i) with an immobilized hydroxide, to thereby provide a composition comprising the monomer of formula I and a cross-linker (page 5, line 26; page 7, lines 5-7; page 11, lines 11-12).

f) Dependent Claim 23

Claim 23, which depends from claim 1, further recites that effective to form a composition comprising the monomer of formula (I) and about 0.50 percent or less of the cross-linker (Figure 2).

g) Dependent Claim 24

Claim 24, which depends from claim 9, which in turn depends from claim 1, further recites the contacting results in formation of P-C(O)-Q, and the passing step is effective to remove said P-C(O)-Q from the composition (page 12, lines 7-16).

h) Dependent Claim 25

Claim 25, which depends from claim 24, which in turn depends from claim 9 and claim 1, further recites the process is effective to provide essentially quantitative conversion of the compound of formula (II) to the monomer of formula (I) (page 12, lines 11-14).

i) Dependent Claim 26

Claim 26, which depends from claim 15, which in turn depends from claim 1, further recites the resulting polymer comprises 5% or less of a polymer formed by polymerization of said cross-linker (page 16, line 15).

j) Dependent Claim 29

Claim 29, which depends from claim 3 reciting the acid is immobilized on an ion exchange resin (page 7, lines 1-2; page 17, lines 27-28; page 20, lines 21-22), which in turn depends from claim 1, further recites that prior to the neutralizing, the immobilized acid is removed by filtration (page 18, lines 5-9).

k) Dependent Claim 30

Claim 30, which depends from claim 1, further recites the polymerizable monomer of formula (I) is glycerine methacrylate (GMA), the compound of formula (II) is 2,2-dimethyl-1,3-dioxolan-4-yl methyl methacrylate (GMAK), the acid by-product is methacrylic acid (MA), and the cross-linker is glycerol dimethacrylate (page 11, lines 15-20; page 17, line 15 to page 18, line 19).

(8) Grounds of Rejection to be Reviewed on Appeal

1) Whether claims 1-6, 9-26, 29, and 30 are unpatentable under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 4,056,496 to Mancini et al. in view of U.S. Patent No. 5,212,015 to Mitra et al. as evident in U.S. Patent No. 3,845,164 to Goto et al. and U.S. Patent No. 6,239,298 to Williamson et al., and further in view of a Rohm and Haas product data sheet on an Amberjet product (November 1998).

(9) Argument

1. Rejection Of Claims 1-6, 9-26, 29, and 30 are unpatentable under 35 U.S.C. §103(a) as being obvious over Mancini et al. (U.S. Patent No. 4,056,496) in view of Mitra et al. (U.S. Patent No. 5,212,015) as evident in Goto et al. (U.S. Patent No. 3,845,164) and Williamson et al. (U.S. Patent No. 6,239,298), and further in view of a Rohm and Haas product data sheet on an Amberjet product.

Claim 1

Claims 1-6, 9-26, 29, and 30 were finally rejected under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 4,056,496 to Mancini et al. (hereinafter "Mancini et al.") in view of U.S. Patent No. 5,212,015 to Mitra et al. (hereinafter "Mitra et al.") as evident in U.S. Patent No. 3,845,164 to Goto et al. (hereinafter "Goto et al.") and U.S. Patent No. 6,239,298 to Williamson et al. (hereinafter "Williamson et al."), and further in view of a Rohm and Haas product data sheet on an Amberjet product (AMBERJET® 1500 H, November 1998)(hereinafter "the Rohm and Haas article").

The Examiner's Position

According to the Final Office Action dated February 25, 2009 (pages 4-7), claims 1-6, 9-26, 29, and 30 are obvious for the following reasons:

> Mancini et al. (col. 3, line 32-48) disclose the deketalization of a compound that is substantially identical to the chemical of Formula II as claimed with a strong acid. Mancini et al. (col. 3, line 50 to col. 4, line 3) in example 1 clearly indicate the use of concentrated sulfuric acid for the deketalization process, which is also followed by a filtration process.
>
> The difference between the invention of claims 1-6, 9-26, 29, 30 and Mancini et al. is that Mancini et al. are silent on using an immobilized acid for the disclosed deketalization process.
>
> Mitra et al. (col. 18, Example 21) disclose a process to deketalize an organic compound. Since both Mancini et al. and Mitra et al. are both related to the same endeavor of deketalizing organic compounds, it would have been obvious to one of ordinary skill in art to appreciate and combine the deketalization teachings in Mitra et al. and Mancini et al. Further, motivated by the expectation of success of

obtaining compounds that are of high purity with Amberlyst-15, which is an immobilized acid (Mitra et al., col. 18, Example 21) comprising sulfonic acid functionalities which are highly acidic by nature, it would have been obvious to one of ordinary skill in art to incorporate the immobilized acid teachings of Mitra et al. into Mancini et al. to obtain the invention of claims 1-6, 9-26, 29, 30.

Regarding the claimed side reaction products, an acrylic acid and a crosslinker, applicants must recognize that deketalized product [sic] of Mancini et al. are prompt [sic] to side reactions in the presence of a strong acid such as the concentrated sulfuric acid of Mancini et al. or the Amberlyst-15 of Mitra et al. In the presence of a strong acid, the hydrolysis of the deketalized product of Mancini et al. would readily lead to the formation of acrylic acid or methacrylic acid as claimed, which is affirmed by the reference to Goto et al. (col. 4, line 34-37). After reviewing the reference to Goto et al., it would not be difficult to one of ordinary skill to recognize that the deketalization of Mancini et al. comprises side reaction products, such as acrylic acid or methacrylic acid as claimed.

In view of the reasons set forth above, reaction mixture [sic] as disclosed in Mancini et al. clearly disclose a reactive mixture comprising deketalized product [sic] of Mancini et al. and acrylic acid or methacrylic acid. In view of the teachings of Williamson et al. (col. 2, line 40-49), it is clearly [sic] that the esterification reaction can readily occur between an alcohol (glycerol) and a free carboxylic acid (acrylic acid) in the presence of a strong acid (sulfuric acid) (col. 3, line 9-14). Therefore, after reviewing the reference to Williamson et al. it would not be difficult to one of ordinary skill to recognize the esterification reaction product produced by the reaction of the deketalization of Mancini et al. with the side reaction products, such as acrylic acid or methacrylic acid, to obtain the crosslinker as claimed.

. . .

The difference between the invention of claims 1-6, 9-26, 29, 30 and Mancini et al. is that Mancini et al. are silent on using an immobilized hydroxide for neutralizing the reaction product.

The Rohm and Haas product literature (page 1, first paragraph) teaches that when an immobilized acid (Amberjet 1500H) is used, it would also be good to use Amberjet 4400 OH to neutralize the medium (reducing the acidity) for regeneration purposes. Motivated by the expectation of success of reducing the acid content in the final product of Mancini et al., it would have been obvious to one of ordinary skill in art to employ the Amberjet 4400 OH teachings (or an immobilized hydroxide) as taught in the Rohm and Haas product literature into [sic] Mancini et al. to obtain the immobilized hydroxide feature as claimed.

Applicants must recognize that Mancini et al. (col. 3, line 50-64) clearly express

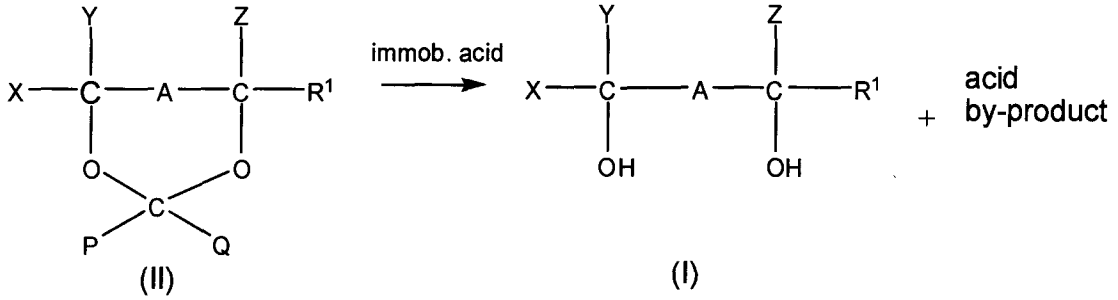
> the desire to reduce the acidity of the reaction by washing the reaction product with water. Since water can be considered a base relative to sulfuric acid, and water (H-O-H) possesses a hydroxyl group as well, the examiner has a reasonable basis that the washing step of Mancini et al. can be considered a neutralization step as well.

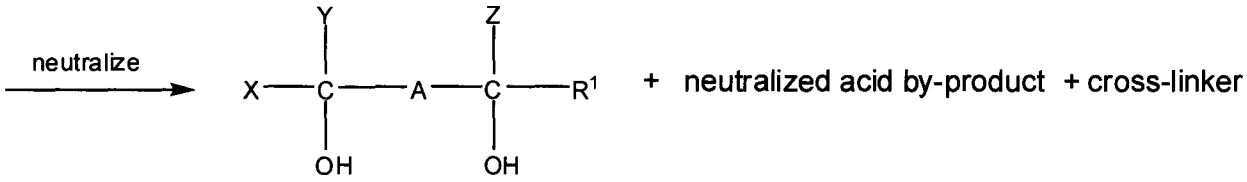
The Appellants' Position

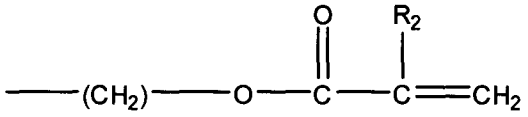
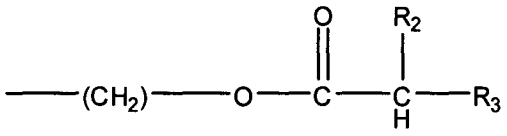
Appellants respectfully submit that claim 1 on appeal is not obvious under 35 U.S.C. §103(a) in view of the five references relied upon by the Examiner. In particular, the five relied upon references, individually or in combination, fail to teach, suggest, or even predict a process of forming a polymerizable composition comprising a polymerizable monomer of formula I as featured in the present invention.

The present claims on appeal are directed to a process for the preparation of a polymerizable composition that is useful, for instance, in the manufacture of contact lenses. For instance, claim 18 recites the step of forming the polymer into an ocular device. As recited in claim 1 on appeal, it is important to note that once the compound of Formula (II) is contacted with an immobilized acid to form the composition comprising the monomer of Formula (I), the composition of step (I) is neutralized with an immobilized hydroxide.

For the Honorable Board's reference and convenience, the claimed process is shown generally in the reaction scheme below, where the first arrow relates to step (i) of claim 1 on appeal and the second arrow relates to step (ii) of claim 1 on appeal.





Variable	Selected From
X	Hydrocarbyl[1], H
Y	Hydrocarbyl, H
Z	Hydrocarbyl, H
P	Hydrocarbyl, H
Q	Hydrocarbyl, H
A	CH_2 or absent
R^1	 Or 

[1] As defined in the present application (page 7, lines 14-15), a "hydrocarbyl group" comprises at least C and H, and may optionally comprise one or more suitable substituents.

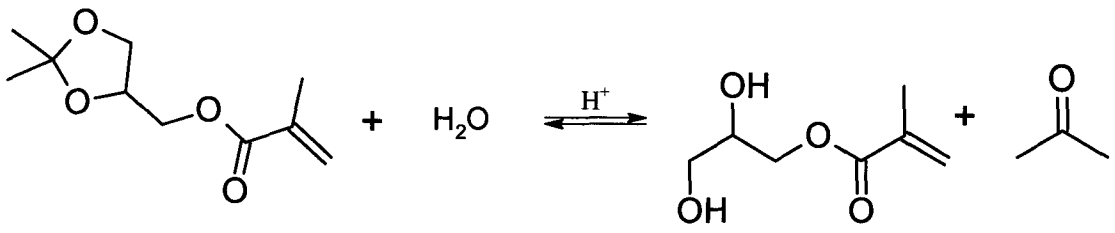
R_2	H, methyl, ethyl, propyl, butyl
R_3	Unsaturated C_{2-5} alkyl

As explained in the present application, in arriving at the claimed process, the inventors recognized the problem of consistently providing/obtaining polymerizable monomer compositions in a satisfactory pure form, i.e., having a very low and quantifiable level of impurities, especially cross-linker impurities (*e.g.*, page 2, line 27 to page 3, line 10). Such impurities are often detrimental to the final polymerized product, and can make such polymers unsuitable for use in biomedical products such as ocular devices. Moreover, polymers are very difficult to purify (*e.g.*, page 4, lines 5-19). The solution provided by the claimed invention is a process, which includes use of a monomeric ketal starting material and an *immobilized acid.* The immobilized acid allows greater control of the reaction kinetics and side reactions, and results in a lower concentration of resulting acidic by-product(s), and following neutralization with an immobilized hydroxide, a lower concentration of cross-linker (*e.g.*, page 6, lines 11-23; page 10, lines 7-11; page 11, lines 25-30). Moreover, the acid can be readily removed to allow facile isolation of the monomer product. The process of the present invention enables ocular devices, for example, to be made more easily, but also it allows, by providing a greater choice of possible degrees and/or rates of cross-linking, greater control over any one of the shrinkage, the dimensional consistency, the swell, the water sensitivity, the hydrophobicity or the hydrophilicity, or combinations thereof, of the resultant polymer (*e.g.*, page 12, line 28 to page 13, line 3). In the Examples section of the present application, a non-limiting process representative of the present invention is illustrated in which product compositions obtained consistently contain a high yield of desired monomer product (*i.e.*, glyceryl methacrylate (GMA)) and a low content of cross-linker (*i.e.*, glycerol dimethacrylate (GDMA)), which monomer product further was shown to be suitable for

production of contact lenses by various shaping techniques (*e.g.*, page 17, line 11 to page 19, line 17).

As admitted in the Final Office Action (page 5), Mancini et al. is silent on using an immobilized acid for the described deketalization process. This difference and others are provided in detail below.

Mancini et al. is directed at least in part to providing hydrogels that have properties suitable for formation of a contact lens or other devices that function in contact with living tissue, and particularly to solving problems associated with the previous lenses at the time of the reference (*See*, *e.g.*, col. 2, lines 45-48; col. 3, lines 1-29; col. 9, lines 24-57). More specifically, Mancini is directed to a polymer formed from a dihydroxyalkyl acrylate, an alkyl acrylate, and an epoxidized alkyl acrylate by a free radical polymerization in the substantial absence of solvent. Mancini describes preparation of GMS as a starting material in Examples 1 and 2. Example 1 describes the following *solution phase* chemistry:



where the ketal, isopropylideneglyceryl methacrylate (GMAK), is reacted with *aqueous* sulfuric acid in the presence of hydroquinone. Excess sulfuric acid is neutralized by addition of barium hydroxide, and the resulting barium hydroxide salt is then removed by filtration.

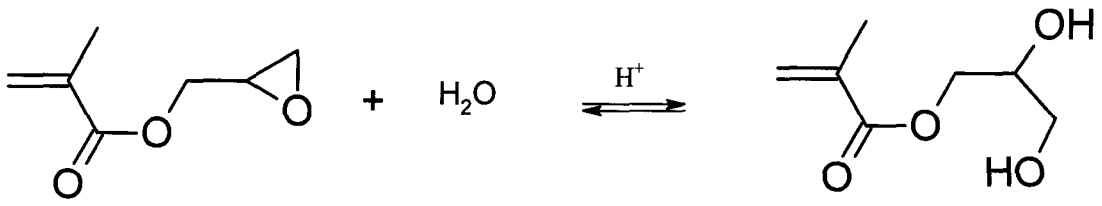
The process and resulting product material of Mancini et al. are different from the present

claims on appeal, including claim 1. The solution phase reaction of Mancini et al. is significantly different from a process standpoint from that embodied by the Appellants' claim 1 on appeal. As acknowledged by the Examiner, Mancini et al. does not relate to the use of an immobilized acid. In particular, Mancini et al. nowhere teaches, suggests, or predicts an outcome for use of an immobilized acid for its deketalization process, nor the potential advantages thereof. Further, nowhere does Mancini et al. teach, suggest, or recognize the formation of methacrylic acid as a side-product (let alone a deleterious one) in the reaction described therein, nor the potential problems associated therewith. Nor does Mancini et al. suggest or even remotely recognize the possibility of formation of *any* amount of a cross-linker during a neutralization step. As also admitted in the Final Office Action (page 6), Mancini et al. is silent on using an immobilized hydroxide for neutralizing any reaction product of the disclosed deketalization process.

Moreover, nowhere does Mancini et al. teach or recognize ANY problem associated with the processes described therein - such as acidifying a ketal monomer precursor under highly acidic conditions, which can lead to significant levels of degradation products and therefore resulting impurities, nor the formation of cross-linker in the subject reaction – which can be highly detrimental to the quality of the resulting monomer product, as well as the final polymer product formed via polymerization of the monomer. Thus, Mancini et al. does not provide the slightest incentive to a person skilled in the art to consider looking elsewhere for possible modifications to the process of Mancini et al., since nowhere does Mancini et al. recognize or suggest even the slightest shortcoming with the methods as described therein.

Indeed, rather than suggesting the use of an immobilized acid, Mancini et al. suggests that a preferred method for preparing glyceryl methacrylate is as provided in Example 2, where GMA is prepared via *solution phase* acid hydrolysis of the epoxidized starting material, glycidyl

methacrylate. This starting material of Mancini et al. has a structure that is completely different than the starting material, formula (II), recited in claim 1 on appeal. The reaction described in Example 2 of Mancini et al. is shown below:



The main impurity noted in the resulting product mixture is unreacted starting material, which Mancini et al. suggests acts *as a cross-linker* (column 5, lines 23-24). Since the subsequent polymerization method of Mancini et al. involves inclusion of an epoxidized alkyl acrylate (believed to be a cross-linker as stated in column 5, lines 23-35), rather than removal of unreacted starting material (e.g., glycidyl methacrylate), Mancini et al. actually suggests an amount of epoxidized acrylate in the monomer composition ranging from 0% to 30% by weight of the dihydroxy acrylate...most preferably from about 3.2 to about 7.5%. Thus, in no way does Mancini et al. suggest a process that focuses on forming small amounts of cross-linker; in contrast, Mancini et al. actually suggests just the opposite, i.e., that *an increase* in epoxidized acrylate cross-linker may be required (column 5, lines 55-61). Thus, Mancini et al. actually teaches away from at least one important feature of the Appellants' claimed method – i.e., minimizing the amount of cross-linker formed.

With respect to "teaching away," the USPTO's reviewing court in *In re Gurley*, 27 F.3d 551, 553, 31 USPQ2d 1130, 1131 (Fed. Cir. 1994) stated:

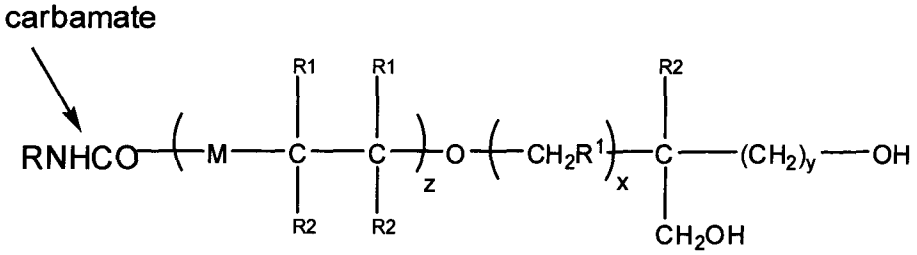
> [a] reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant.

As indicated, a person of ordinary skill, upon reading Mancini et al., would be led in a direction divergent from the path that was taken by the Appellants at least with respect to minimizing the amount of cross-linker formed. The Supreme Court in *KSR* approvingly cited *United States v. Adams*, 383 U.S. 39, 51-52 (1966), for the "principle that when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious." *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1739-40 (2007); 82 USPQ2d 1385 (2007). Therefore, as Mancini et al. teaches providing increased cross-linker instead of decreased amounts, this is evidence that the Examiner's proposed modification of Mancini et al. in view of Mitra et al. and the Rohm and Haas article is more likely to be nonobvious.

In considering Mancini et al. as a whole, in no way does Mancini et al. provide the slightest motivation for using an immobilized acid for any purpose, let alone for reducing side reactions and/or for reducing the amount of acidic and cross-linker reaction side-products. Neither Mitra et al. or the Rohm and Haas article, nor the evidence references of Goto et al. and Williamson et al., compensate for these deficiencies of the primary reference relative to claim 1 on appeal.

Mitra et al. is directed to synthetic routes for providing single isomers of monocarbamate diols, as well as their polymerization. Mitra et al. is focused on a problem that is completely unrelated to the process of Mancini et al., or the present claims on appeal – Mitra et al. is directed to the provision of *isomerically pure* monocarbamate diols that are designed to be used in nonlinear optic applications that are not living tissue environments. Mitra et al. describes that isomerically pure monocarbamate diols can be prepared by acidification of the corresponding ketals. Mitra et al. further describes that acidification can be carried out using an organic or non-

oxidizing inorganic acid, or even using an ion exchange resin. While Mitra et al. is related to providing pure compounds in a very general sense, the applied focus of Mitra et al. is the provision of *isomerically* pure compounds – not compounds having a greater degree of purity related to low levels of acidic and cross-linker impurities. More specifically, Mitra et al. relates to preparing isomerically pure compounds having the general formula:



These compounds are structurally dissimilar from the monomer of formula (I) recited in the Appellants' claim 1 on appeal, nor has the Examiner explained with explicit analysis how they may correspond to any compounds in the process described by Mancini et al. These isomers of monocarbamate diols made by the processes described in Mitra et al. do not correspond to the hydrogels made by the process of Mancini et al.

The Examiner's assertion in the Final Office Action (page 5) that the combination of Mancini et al. and Mitra et al. is proper since Mancini et al. and Mitra et al. are both related to the same endeavor of deketalizing organic compounds is flawed. As indicated, Mitra et al. has absolutely nothing to do with preparing compounds having the structures described in Mancini et al., nor those recited in the instant claims of appeal. Nor is there any expectation of success in obtaining compounds made by the process of the present claims if the alleged immobilized acid teachings of Mitra et al. were somehow incorporated into the different process of Mancini et al. (as proposed in the Final Office Action (page 5)).

Evidence showing the unpredictable nature of any proposed combinations of Mancini et al.

and Mitra et al. includes the fact that the Examiner's cited combination of these references combines different processes occurring in different contexts, using different reactants, with different results aimed at solving different objectives or problems. The products of Mitra et al. are stated to be particularly useful in nonlinear optics (NLO), and are useful in nonlinear optical devices, such as second harmonic generators, such as an optical switch or light modulation device (*e.g.*, laser devices)(*See, e.g.*, col. 1, lines 18-20; col. 2, lines 52-68; col. 4, lines 34-54; col. 15, lines 56-59). Clearly, Mitra et al. does not teach, suggest, or predict the process and any process steps described therein for making monocarbamate diols have any application to processes for making biomedical devices suitable for use in contact with living tissue, such as contact lenses. The Appellants again point out that Mancini et al., the primary reference, specifically relates to monomers and hydrogels for contact lenses, which would be a pharmaceutical or medical use. This use is not mentioned, suggested, or predicted in Mitra et al.

Further, the Examiner has not established with evidence or scientific reasoning why a person skilled in the art would have sought to solve a problem that is *unrecognized* by Mancini et al., *viz.*, overproduction of acid and cross-linker reaction side-products, by looking to any "immobilized acid teachings" of Mitra et al. Mitra et al. fails to teach, suggest, or predict an outcome for minimizing formation of either acid or cross-linker reaction by-products during formation of a product having the structure of Appellants' formula (I). As indicated, Mitra et al. describes solutions applied to the field of optical switches and laser devices and similar nonlinear optical devices, but not to the separate field of contact lenses used in contact with living tissue, such as relevant to Mancini et al. (and embodiments of the present invention). The Examiner has not shown with evidence or scientific reasoning that Mitra et al. provides solutions to any problems associated with production of polymers for nonlinear optical devices that a person of

ordinary skill in the art would consider relevant and applicable to the dekelatization reactions of Mancini et al. used to form monomers useful in the preparation of contact lenses. Thus, a combination of Mancini et al. and Mitra et al., such as proposed by the Examiner, should not be expected to result in the present invention as a predictable outcome thereof.

Further, in view of the widely divergent subject matter, i.e., the particular chemical compounds, processes, results, and desired products, that are the subjects of Mancini et al. and Mitra et al., it is submitted that the combination of references proposed by the Examiner in the final rejection is based, not upon some motivation provided by either of the references themselves or some other valid apparent reason, nor by an acknowledgement in either reference of a problem to be solved that is similar in nature to that addressed by the Appellant, but rather, solely upon the Appellants' own disclosure – in an attempt to arrive at the subject matter of the Appellants' claims – which the references, when combined, clearly fail to do.

The Examiner also has relied upon Goto et al. and Williamson et al. as "evidence" type references. As stated, in relevant part, in M.P.E.P. § 2112, IV:

> ... "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted) ...

Goto et al. does not teach any recognized problems that are necessarily associated with acrylic acids and cross-linker reaction side-products *in the context of deketalization reactions*. That information comes only from the present application. The Examiner has relied upon Goto et al. at column 4, lines 34-37, for stating the following, "[t]he pH of the polymerization system ranges from 5-9, especially 6-8. If the pH is outside of the indicated range, hydrolysis of methyl

methacrylate occurs to yield methacrylic acid, resulting in an unstable system" (Final Office Action, pages 5-6). However, that phrase must be understood in the overall context of the Goto et al. reference. Goto et al. is directed to a mixed resin composition and a method of preparing the same. The method involves polymerization of 85% by weight 1,3-butadiene, 5-30% by weight styrene, 3-40% by weight methylmethacrylate, and 0.1-1% by weight of a divinyl compound to form latex particles. The latex particles are then further modified by graft polymerizing thereupon a monomer mixture containing particular weight ranges of methylmethacrylate, styrene, and acrylonitrile, followed by blending the resulting graft copolymer with 95-75 parts by weight of a vinyl chloride polymer. The resulting compositions are stated to be useful for blow-molding, a process employed to make hollow plastic devices. Further, the Goto et al. patent is directed to (i) overcoming the problem of graft polymer products, which develop stress whitening upon the application of force, and (ii) providing blow molded products without the formation of uneven or irregular surfaces. Clearly, the manufacturing process described in Goto et al., the chemical compositions employed, as well as those ultimately formed, and the problems addressed in Goto et al. have nothing to do with deketalization reactions of Mancini et al. Goto et al. is not extrinsic evidence that makes clear that missing descriptive matter of Mancini et al. with respect to undesirable acrylic and cross-linker reaction side-products is necessarily present in the reaction products described in the reference and were recognized as such in the prior art.

Further, as to the above-noted phrase at col. 4, lines 34-37 of Goto et al., a person of ordinary skill in the art would more naturally read that description as an admonition to keep the pH of the polymerization system *within* the stated pH range of 5-9, especially 6-8, to avoid instability issues, and as a clear *disincentive* to a person of ordinary skill to consider looking for ways to use or try to modify strongly acidic deketalization reaction systems. The Examiner's assertion in the

Final Office Action (pages 5-6) that "it would not be difficult to one of ordinary skill to recognize that the deketalization of Mancini et al. comprises side reaction products ... as claimed" is technically flawed for the reasons explained above. Goto et al. fails to make up the deficiencies of Mancini et al. and Mitra et al. as characterized above, when considered either singly or in combination therewith. Further, Goto et al. teaches away from the present invention.

Williamson et al. is directed to a fuel lubricity additive. Specifically, Williamson et al. is directed to a synthetic method for preparing a fuel lubricity additive by reacting an unsaturated base oil from vegetable oil sources with a carboxylic acid-diene compound, followed by esterifying or amidifying the carboxylic acid functionality with either a poly-hydroxy or a poly-amine compound to form the final fuel additive. Fig. 1 in Williamson et al. illustrates the structure of an illustrative fuel additive as provided therein. As in the case of the Goto et al., Williamson et al. has no relevance to the deketalization reactions of Mancini et al., nor does Williamson et al. shed light on any problems that may be arising in the reactions of Mancini et al. that may need attention. The chemical synthesis described by Williamson et al. involves completely different classes of chemical compounds, transformation reactions, and ultimate products from those described by Mancini et al. Williamson et al. is not extrinsic evidence that makes clear that missing descriptive matter of Mancini et al. with respect to undesirable acrylic and cross-linker reaction side-products is necessarily present in the reaction products described in the reference and were recognized as such in the prior art. Further, nothing in the Williamson et al. reference is even remotely related to the Appellants' process for forming a polymerizable monomer, nor to the use of an immobilized acid, nor to a reaction in which the amount of cross-linker formed is minimal by virtue of the reaction conditions employed. Therefore, the Williamson et al. reference fails, as does Goto et al., to make up for the deficiencies of Mancini et al. and Mitra et al., nor evidence the

inherent presence of acid and cross-linker reaction side-products in the reaction products of Mancini et al.

With respect to the recitations of present claim 1(ii), the Examiner admitted in the Final Office Action that Mancini et al. is silent on using an immobilized hydroxide for neutralizing the reaction product, yet alleges that this feature would have been obvious over the Rohm and Haas article, and, additionally, the Examiner is understood to suggest that this feature inherently occurs in the washing step of the process of Mancini et al. (Final Office Action, pages 6-7).

The Examiner's reliance on the Rohm and Haas article is flawed. The Rohm and Haas article relates to industrial uses and particularly for mixed bed applications "commonly encountered in power plant, high flow rate condensate polishing." Further, at page 2 of the Rohm and Haas article, there is a section entitled, "LIMITS OF USE." In this Rohm and Haas article, it explicitly states that Amberjet 1500 H is suitable for industrial uses, but for other uses, such as pharmaceutical, food processing, or potable water applications, Amberjet 1500 H is not recommended and actually states that one should contact Rohm and Haas for recommendations. The Rohm and Haas article, therefore, affirmatively discourages a person of ordinary skill from considering use of the Amberjet 1500 H product for non-industrial uses, which would include the uses such as those of Mancini et al. (*e.g.*, contact lenses). Therefore, the Rohm and Haas article teaches away from the present invention. *In re Gurley*, 27 F.3d at 553. The Rohm and Haas article, therefore, is evidence of the non-obviousness of the present claims on appeal.

Further, the Examiner's allegation in the Final Office Action that the term "pharmaceutical" used in the Rohm and Haas article means "drug related" (and, apparently, according to the Examiner, thus does not refer or apply to contact lenses), is unsupported by any evidence of record (*See*, page 9 of Final Office Action). As well known in the ophthalmic lens

industry, Federal law (and also state law, where applicable), requires a valid prescription from an eye doctor before any contact lens can be dispensed. As also well known in the industry, contact lenses are medical devices that are regulated by the US FDA.

As indicated, Mancini et al., and embodiments of the present invention, relate to ocular devices. As indicated above, the Examiner has no reasonable basis to dispute the fact that the Rohm and Haas article does expressly teach away from the claimed invention. Clearly, one skilled in the art reading Mancini et al. in forming contact lenses (a medical-related use and product) would in no way be encouraged or motivated to use the Amberjet 1500 H in the production of any such product, and particularly not in conjunction with any use of Amberjet 4400 OH in the manner proposed in the final rejection. In fact, as indicated, the Rohm and Haas article, i.e., the Amberjet 1500 H brochure, cautions against doing any medical/pharmaceutical uses and the Examiner is disregarding this warning in making this rejection.

Further, the Appellants also submit that the Examiner's argument is flawed regarding the Rohm and Haas article teaching the use of any immobilized acid and the neutralization of any medium (Final Office Action, page 7). The Rohm and Haas article is quite specific. The Rohm and Haas article only and strictly mentions Amberjet 1500 and not any immobilized acid, and further only Amberjet 4400 OH is mentioned, and it is not mentioned to neutralize any "medium." The Rohm and Haas article specifically states that the Amberjet 4400 OH is to be used in mixed bed applications with Amberjet 1500 for industrial uses. No neutralization is mentioned. Further, a mixed bed application needs to be understood with regard to this rejection. A mixed bed application means that the Amberjet 1500 H is present with the Amberjet 4400 OH in the same bed for purposes of a reverse-flow operation. This type of use, namely a mixed-bed application, is clearly not the type of process occurring in Mancini et al. and, specifically, in Example 1, which is

the part referred to by the Examiner. In fact, Example 1 of Mancini et al. does not describe any use of a bed of immobilized acid and certainly does not teach or suggest the combination of an immobilized acid and immobilized hydroxide. This type of use simply would not make "common sense" in Example 1 of Mancini et al., especially considering the guidance provided in the Supreme Court decision of *KSR International Co.*

The Examiner's additional assertion that the use of an immobilized hydroxide for neutralizing the reaction product, although not taught by Mancini et al., inherently occurs in the washing step of the process of Mancini et al., is flawed (Pages 6-7 of the Final Office Action). In this respect, the Appellants submit that the Examiner's characterization regarding the purpose and function of the water used in Example 1 ("col. 3, lines 50-64") of Mancini et al. is clearly flawed (Final Office Action, pages 7, 11). It is apparent that the washing with water of Mancini et al. is simply used to remove any residual "solution" from the precipitate (barium sulfate). Example 1 of Mancini et al. explicitly states that the filtrate and "washings" are combined to give the solution which is then isolated. There is no teaching in Mancini et al. that the washings with water are used to neutralize any acid, nor would that be technically expected to occur, and it is clear that the use of water is simply to obtain any "solution" on the precipitate. Yet, in the Final Office Action, the Examiner alleges (twice) that "[s]ince water can be considered a base relative to sulfuric acid, and water (H-O-H) possesses a hydroxyl group as well, the Examiner has a reasonable basis that the washing step of Mancini et al. can be considered a neutralization step as well" (*See*, pages 7 and 11 of the Final Office Action). As cited in M.P.E.P. § 2144.03, A:

> ... *In re Grose*, 592 F.2d 1161, 1167-68, 201 USPQ 57, 63 (CCPA 1979) ("[W]hen the PTO seeks to rely upon a chemical theory, in establishing a prima facie case of obviousness, it must provide evidentiary support for the existence and meaning of that theory.") ...

The Examiner provides no such evidentiary support for the existence and meaning of the Examiner's above-indicated theory that "water" is a source of acid-neutralizing hydroxide ions relative to sulfuric acid, other than the Examiner's own conclusory statement. Further, the Appellants point out that it is a scientifically known fact that pure water (H_2O) has a pH value of 7.0. By definition, a neutral pH material will not neutralize an acid or a base. It may possibly dilute it, but that is not neutralization in a chemical sense. It further is a scientifically known fact that water can contain very small, but e*qual*, amounts of hydronium ions (H_3O^+) and hydroxide ions (OH^-). In any event, based on such well-known scientific facts, pure water would not have excess hydroxide ions available effective to neutralize an acid, particularly a strong acid such as sulfuric acid, intentionally or by accident.

Therefore, Mancini et al. fails to teach or suggest, inherently or expressly, using an immobilized hydroxide for neutralizing the reaction product. Mancini et al. thus cannot meet the recitations of step (ii) of present claim 1 on appeal. The Final Office Action does not suggest that any of Mitra et al., the Rohm and Haas article, Goto et al., or Williamson et al. references relied upon in the final rejection meet the recitations of step (ii) of claim 1 on appeal. Therefore, the secondary references of the final rejection fail to compensate for at least this deficiency of Mancini et al. relative to claim 1 on appeal. To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). In the present appeal, the Examiner has not shown that all of the words and limitations in claim 1 are present in the five relied upon references, including with respect to the recitations of step (ii).

In considering the primary reference relied upon by the Examiner, Mancini et al., as a whole, it can be seen that:

(i) Mancini et al. fails to teach or suggest use of an immobilized acid;

(ii) Mancini et al. fails to recognize the possibility of formation of an acidic by-product during acidification of a ketal starting material to form a corresponding diol, and more importantly, the problems associated therewith;

(iii) Mancini et al. fails to recognize the possibility of formation of a cross-linker side-product during neutralization of an acidic product mixture resulting from acidification of a ketal starting material, and more importantly, the problems associated therewith, and the desirability of reducing the levels of such a cross-linker in the resulting monomer product;

(iv) Mancini et al. fails to teach or suggest use of an immobilized hydroxide to neutralize the composition comprising the monomer of formula (I); and

(v) Mancini et al. even *teaches away* from the essence of the Appellants' claims by pointing to the desirability of a reaction that actually forms significant amounts of cross-linker.

Clearly, numerous significant differences are present between the primary reference of Mancini et al. and claim 1 on appeal.

As stated by the Supreme Court: "[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR,* 127 S.Ct. at 1740-41 (quoting *In re Kahn,* 441 F.3d 977, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)).

In view of the Appellants' comments above, it can be seen that the Examiner has not articulated reasoning with some rational underpinning for modifying the alleged teachings of Mancini et al. in view of the secondary references of Mitra et al., the Rohm and Haas article, Goto et al., and Williamson et al., to arrive at the Appellants' claimed method. While each of these references does describe some chemical synthesis, none of these references is even remotely

related to the process embodied by the Appellants' claims, nor the problems addressed by such claims, nor the particular polymerizable monomer formed as a product, as described in detail above. Further, none of the five references used in the final rejection, when considered either singly or in combination, points to the desirability of using an immobilized acid, and then an immobilized hydroxide, in a method such as that presently claimed.

In view of these reasons, claim 1 on appeal is not *prima facie* obvious over Mancini et al., Mitra et al., the Rohm and Haas article, Goto et al., and Williamson et al.

Claims 2-6, 9-21, 23-26, 29, and 30, which depend from claim 1, are not *prima facie* obvious over these five references for at least the same reasons as their parent claim. These claims also set forth additional features which further describe and define embodiments of the present invention that are not obvious under 35 U.S.C. § 103(a) over Mancini et al., Mitra et al., the Rohm and Haas article, Goto et al., and Williamson et al. A number of these claims are specifically further discussed below.

For these reasons, this rejection should be reversed.

Claim 9

Claim 9, which depends from claim 1, further recites that prior to the contacting, the immobilized acid is contained, and after said contacting, passing a gas through the contained immobilized acid.

In the final rejection, the Examiner has not articulated an "explicit" analysis on why the recitations of claim 9 are considered obvious by the Examiner over Mancini et al., Mitra et al., the Rohm and Haas article, Goto et al., and Williamson et al. *KSR*, 127 S.Ct. at 1741. "[T]here must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *Id.* (quoting *In re Kahn).*

In view of the above comments, Appellants respectfully request reversal of the rejection of claim 9 for this additional reason.

Claims 18 and 21

Claim 18 depends from claim 15, which depends from claim 1, and further recites forming the polymer formed in the polymerizing step into an ocular device. Claim 21 recites an ocular device comprising the polymer formed by the process of claim 15.

As indicated, Mancini et al. fails to use an immobilized acid as recited in claim 1 on appeal in the production of hydrogels for contact lenses, amongst other differences. Mitra et al. widely diverges from Mancini et al. The isomers of monocarbamate diols described by Mitra et al. do not correspond to the hydrogels of Mancini et al. Nor is there any expectation of success in obtaining the same compounds used in the ocular devices of present claim 18 or 21 if the alleged "immobilized acid teachings" of Mitra et al. were somehow incorporated into the different process of Mancini et al. As indicated, the products of Mitra et al. are stated to be particularly useful in nonlinear optics (NLO), and are useful in nonlinear optical devices, such as second harmonic generators, such as an optical switch or light modulation device (*e.g.*, laser devices). Clearly, Mitra et al. does not teach, suggest, or predict the process and any process steps described therein for making monocarbamate diols have any application to processes for making biomedical devices suitable for use in contact with living tissue, such as contact lenses.

In view of the above comments, Appellants respectfully request reversal of the rejection of claims 18 and 21 for this additional reason.

Claim 22

Independent claim 22 is directed to a process for the preparation of a polymerizable composition comprising a polymerizable monomer of formula I, which has similar recitations as claim 1 on appeal, wherein the immobilized acid is also defined in claim 22 as having a pK_a of less than 3, and X and Y are defined as independently selected from hydrocarbon groups having 1 to 20 carbon atoms and hydrogen.

Claim 22 is non-obvious over Mancini et al., Mitra et al., the Rohm and Haas article, Goto et al., and Williamson et al., for at least the same reasons as indicated above by Appellants for claim 1 on appeal.

Claim 22 on appeal specifies the immobilized acid is further defined as having a pK_a of less than 3. The present application defines a "strong acid' as an acid having a pK_a of less than 3 (page 6, lines 29-30). None of these five references used in the final rejection, when considered either singly or in combination, points to the desirability of using a strong immobilized acid, and then an immobilized hydroxide, in a method such as that presently claimed. As indicated, for example, col. 4, lines 34-37 of Goto et al. would more naturally be read by a person of ordinary skill in the art as an admonition to keep the pH of the polymerization system within the stated pH range of 5-9, especially 6-8, to avoid instability issues, and not as an incentive for a person of ordinary skill to look for ways to use or try to modify strongly acidic deketalization reaction systems, such as those using a strong immobilized acid having a pK_a of less than 3. Therefore, Goto et al. teaches away from claim 22 on appeal by encouraging persons of ordinary skill to avoid the use of strong acids in order to maintain stability of the polymerization system. The process of the present invention succeeds using a strong immobilized acid, such as shown in the examples of the present application.

In view of at least these reasons, claim 22 on appeal is not *prima facie* obvious over

Mancini et al., Mitra et al., the Rohm and Haas article, Goto et al., and Williamson et al.

For these reasons, this rejection should be reversed.

Claims 23, 25, and 26

The Examiner specifically stated in the Final Office Action (page 6) that claims 23, 25, and 26 were not patentable for the following reasons:

> Regarding the claimed "0.50 percent of less of crosslinker" [sic] of claim 23, the "essentially quantitative conversion" of claim 25, the "5% or less of a polymer formed by polymerization of said crosslinker" of claim 26, in view of the substantially identical type of reaction as disclosed in the prior art and the reaction type as claimed, the examiner has a reasonable basis that the claimed amount of side reaction product or the "essentially quantitative conversion" are inherently possessed in Mancini et al. and Mitra et al.

The Appellants submit that the Examiner's assertion that the art relied upon provides reasonable basis for this assertion is flawed. In turning to Mancini et al. and examining the experimental results described therein, it can be seen that Example 1 of Mancini et al. fails to provide any yield or characterization data for the monomer formed. Example 2 of Mancini et al. describes reaction of 100 grams of glycidyl methacrylate in the presence of concentrated sulfuric acid, followed by neutralization with a base. 18.8 grams (nearly 20%) of unreacted starting material is recovered from the process – this can hardly be said to render inherent the feature of claim 25, which recites essentially *quantitative conversion* of starting material to product. Moreover, Example 2 fails to provide any analytical data at all for the resulting product mixture – thus, there is no basis for the assumption by the Examiner that the feature recited in Appellants' claim 23, i.e., formation of about 0.50 percent or less of cross-linker, is a feature of Example 2, in particular in view of the fact that Mancini et al. fails to even recognize the problems associated with cross-linker formation. Indeed, the Appellants discuss Mancini et al. and the shortcomings thereof in the present application at page 3, line 25 to page 4, line 3. Finally, the Examples in

Mancini et al. describing polymerization with a co-monomer (Examples 3-47) fail to provide any data whatsoever regarding the purity of the resulting polymer product, i.e., the formation of polymer products resulting from polymerization of a cross-linker. As indicated, Mitra et al. fails to describe reactions of the type embodied in the Appellants' claims, and therefore is irrelevant to the present analysis.

In view of these reasons, there is no reasonable basis in the art relied upon by the Examiner for the assertion that the features recited in claims 23, 25, and 26 on appeal are inherent in the art used in the final rejection.

In view of the above comments, Appellants respectfully request reversal of the rejection of claims 23, 25, and 26 for this additional reason.

Claim 24

Claim 24, which depends from claim 9, which in turn depends from claim 1, further recites the contacting results in formation of P-C(O)-Q, and the passing step is effective to remove said P-C(O)-Q from the composition.

In the final rejection, the Examiner has not articulated an "explicit" analysis on why the recitations of claim 24 are considered obvious by the Examiner over Mancini et al., Mitra et al., the Rohm and Haas article, Goto et al., and Williamson et al. *KSR*, 127 S.Ct. at 1741.

In view of the above comments, Appellants respectfully request reversal of the rejection of claim 24 for this additional reason.

Claim 29

Claim 29 depends from claim 3, which depends from claim 1, and specifically recites that prior to neutralizing, the immobilized acid is removed by filtration. The Examiner has considered claim 29 to be obvious in view of at least the following reasons (Final Office Action, page 8):

> Regarding applicants' argument that the prior art is silent on the feature of claim 29 which claims that prior to neutralizing, the immobilized acid is removed by filtration, applicants must recognize that the rationale set forth by the examiner is adequate since claim 29 does not state which of the components after filtration is being neutralized. Applicants must recognize that Mancini et al. (col. 3, line 50-64) clearly express the desire to reduce the acidity of the reaction by washing the reaction product with water. Since water can be considered a base relative to sulfuric acid, and water (H-O-H) possesses a hydroxyl group as well, the examiner has a reasonable basis that the washing step of Mancini et al. can be considered a neutralization step as well.

The Examiner's allegation that the washing step of Mancini et al. can be considered a neutralization step, *i.e.*, the Examiner alleges that water neutralizes sulfuric acid, has been shown to be flawed by Appellants' in their comments made above in their discussion of claim 1, which are equally applicable here and reference is made thereto. Further, since claim 29 ultimately depends from claim 1, it is quite clear from the present claims "which of the components after filtration is being neutralized" – it is "the composition of step (i)" without the immobilized acid.

Further, the recitation in claim 29 on appeal of that "prior to said neutralizing, said immobilized acid is removed by filtration" is different from a mixed-bed operation as specifically described for the use of Amberjet 1500 H in combination with Amberjet 4400 OH in the Rohm and Haas article. As discussed above, claim 1 on appeal, for instance, states that the composition of step i) is neutralized with the immobilized hydroxide to provide the composition comprising the monomer of Formula (I) and a cross-linker. Thus, the immobilized hydroxide neutralizes the composition and this is clearly not mentioned or suggested in any of the references cited by the Examiner, including the Rohm and Haas article. The Rohm and Haas article merely states using specifically Amberjet 4400 OH with Amberjet 1500 H for mixed-bed applications and there is no suggestion to use an immobilized acid on a polymer product itself, after forming the product. The Examiner's reasoning in this respect would appear to be based on hindsight alone, especially since

the Rohm and Haas article simply would not be combinable with the particular processes and uses of the primary and secondary references as mentioned above. It appears that the Examiner has improperly relied on hindsight analysis of the Appellants' own disclosure to reach a conclusion of obviousness (*See*, *e.g.*, M.P.E.P. §2142). Further, as explained above, the Examiner's characterization regarding the purpose and function of the water used in Example 1 ("col. 3, lines 50-64") of Mancini et al., *i.e.*, the Examiner's allegation that water used in washings neutralizes sulfuric acid, is clearly flawed.

In view of the above comments, Appellants respectfully request reversal of the rejection of claim 29 for this additional reason.

Claim 30

Claim 30, which depends from claim 1, further recites the polymerizable monomer of formula (I) is glycerine methacrylate (GMA), the compound of formula (II) is 2,2-dimethyl-1,3-dioxolan-4-yl methyl methacrylate (GMAK), the acid by-product is methacrylic acid (MA), and the cross-linker is glycerol dimethacrylate.

In the final rejection, the Examiner has not articulated an "explicit" analysis on why the recitations of claim 30 are considered obvious by the Examiner over Mancini et al., Mitra et al., the Rohm and Haas article, Goto et al., and Williamson et al.

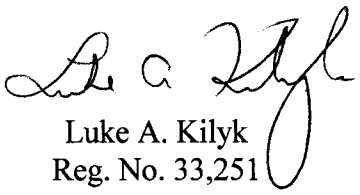
In view of the above comments, Appellants respectfully request reversal of the rejection of claim 30 for this additional reason.

Conclusion

For the reasons set forth above, the Appellants submit that the claims presently pending in the above-captioned application meet all of the requirements of patentability. It is therefore

respectfully requested that the Honorable Board reverse the Examiner and remand this application for issue.

Respectfully submitted,



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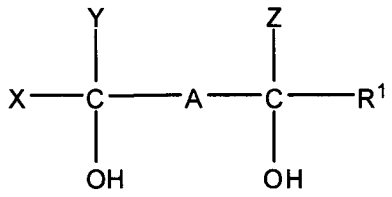
(10) Claims Appendix

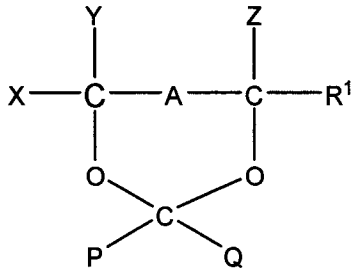
1. A process for the preparation of a polymerizable composition comprising polymerizable monomer of formula I:



(I)

said process comprising the steps of:

(i) contacting a compound of formula II



(II)

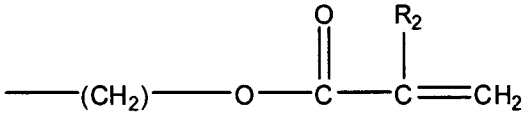
with an immobilized acid to thereby form a composition comprising the monomer of formula (I) and an acid by-product thereof,

wherein

X, Y, Z, P, and Q are independently selected from a hydrocarbyl group or hydrogen,

A is $(CH_2)_n$, wherein n is 0 or 1;

R^1 corresponds to either formula IIIA or formula IIIB



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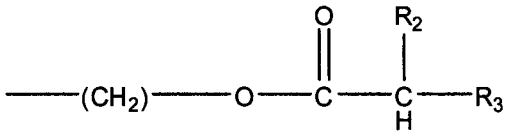

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where R_2 is selected from the group consisting of H, methyl, ethyl, propyl, and butyl, and

and

R_3 is an unsaturated C_{2-5} alkyl; and

(ii) neutralizing the composition of step (i) with an immobilized hydroxide, to thereby provide a composition comprising the monomer of formula I and a cross-linker.

2. A process according to claim 1 wherein the immobilized acid is a strong acid.

3. A process according to claim 1 wherein the acid is immobilized on an ion exchange resin.

4. A process according to claim 1 wherein X and Y are independently selected from hydrocarbon groups having from 1 to 20 carbon atoms and hydrogen.

5. A process according to claim 1 wherein R^1 corresponds to formula IIIA, and R_2 is CH_3.

6. A process according to claim 1 wherein X is H; Y is H, Z is H, n=0, R^1 corresponds to formula IIIA, and R_2 is CH_3.

9. A process according to claim 1, wherein prior to said said contacting, the immobilized acid is contained, and after said contacting, passing a gas through the contained immobilized acid.

10. A process according to claim 9 wherein the gas is air.

11. A process according to claim 9 wherein the immobilized acid is contacted with the compound of formula II in the absence of an organic solvent.

12. A process according to claim 1, wherein said contacting is performed in the presence of water.

13. A process according to claim 9, wherein prior to said contacting, the immobilized acid is contained in a fluidized bed reactor.

14. A process according to claim 9, further comprising after said passing step, extracting the gas from the contained immobilized acid.

15. A process according to claim 1, further comprising, after said neutralizing, polymerizing the composition formed in step (ii), to thereby form a polymer.

16. A process according to claim 1, wherein said acid by-product formed in step (i) is methacrylic acid.

17. A process according to claim 1, wherein said acid by-product formed in step (i) is acrylic acid.

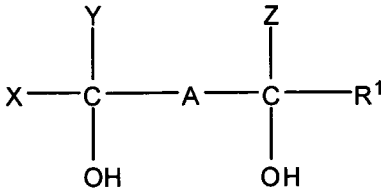
18. A process according to claim 15, further comprising forming the polymer formed in said polymerizing step into an ocular device.

19. A polymerizable monomer or composition formed by the process of claim 1.

20. A polymer formed by the process of claim 15.

21. An ocular device comprising the polymer formed by the process of claim 15.

22. A process for the preparation of a polymerizable composition comprising a polymerizable monomer of formula I:



(I)

said process comprising the steps of:

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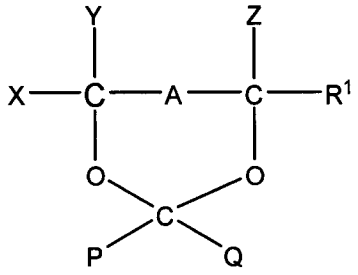


(II)

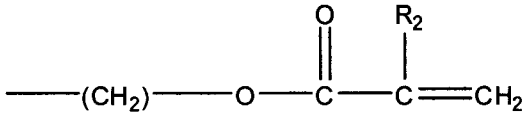
with an immobilized acid having a pK_a of less than 3 to thereby form a composition comprising the monomer of formula (I) and an acid by-product thereof,

wherein

X and Y are independently selected from hydrocarbon groups having 1 to 20 carbon atoms and hydrogen,

Z, P, and Q are independently selected from a hydrocarbyl group or hydrogen, A is $(CH_2)_n$, wherein n is 0 or 1;

R^1 corresponds to either formula IIIA or formula IIIB



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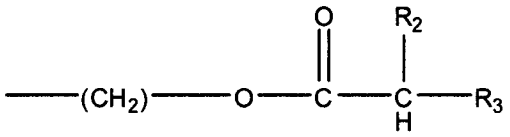

IIIB

where R_2 is selected from the group consisting of H, methyl, ethyl, propyl, and butyl, and R_3 is an unsaturated $C_{2\text{-}5}$ alkyl; and

(ii) neutralizing the composition of step (i) with an immobilized hydroxide, to thereby provide a composition comprising the monomer of formula I and a cross-linker.

23. The process of claim 1, effective to form a composition comprising said monomer of formula (I) and about 0.50 percent or less of said cross-linker.

24. The process of claim 9, wherein said contacting results in formation of P-C(O)-Q, and said passing step is effective to remove said P-C(O)-Q from said composition.

25. The process of claim 24, wherein said process is effective to provide essentially quantitative conversion of the compound of formula (II) to the monomer of formula (I).

26. The process of claim 15, wherein the resulting polymer comprises 5% or less of a polymer formed by polymerization of said cross-linker.

29. The process of claim 3, wherein prior to said neutralizing, said immobilized acid is removed by filtration.

30. The process of claim 1, wherein the polymerizable monomer of formula (I) is glycerine methacrylate (GMA), the compound of formula (II) is 2,2-dimethyl-1,3-dioxolan-4-yl methyl methacrylate (GMAK), the acid by-product is methacrylic acid (MA), and the cross-linker is glycerol dimethacrylate.

(11) Evidence Appendix

None.

(12) Related Proceeding Appendix

None.